

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**



⑫ **EUROPEAN PATENT APPLICATION**

⑳ Application number : **91307376.3**

⑤① Int. Cl.<sup>5</sup> : **A61F 2/02**

㉔ Date of filing : **09.08.91**

③① Priority : **14.08.90 US 566768**

④③ Date of publication of application :  
**26.02.92 Bulletin 92/09**

⑧④ Designated Contracting States :  
**AT BE CH DE DK ES FR GB GR IT LI LU NL SE**

⑦① Applicant : **Cook Incorporated**  
**925 South Curry Pike P.O. Box 489**  
**Bloomington Indiana 47402 (US)**

⑦② Inventor : **Gunther, Rolf**  
**Steinbergweg**  
**W-5100 Aachen (DE)**  
Inventor : **Bates, Brian L.**  
**2313 Rock Creek Drive**  
**Bloomington, Indiana 47401 (US)**

⑦④ Representative : **Bannerman, David Gardner et**  
**al**  
**Withers & Rogers 4 Dyer's Buildings Holborn**  
**London, EC1N 2JT (GB)**

⑤④ **Apparatus for filtering blood in a blood vessel of a patient.**

⑤⑦ An apparatus (10) for filtering blood in a blood vessel of a patient comprises a catheter (30) which is introduced into the blood vessel and advanced to a desired location within the blood vessel, a positioning means (12) having a filter (13) distally attached thereto to be guided through the catheter. In use, the filter is positioned at a location beyond the distal end of the catheter within the blood vessel with the positioning means. The positioning means is then locked to the catheter. The catheter is then anchored to an object located outside of the blood vessel. Thereafter, an amount of blood is filtered within the blood vessel with the filter. The filter can be readily repositioned by unlocking the positioning means from the catheter, repositioning the filter within the blood vessel with the positioning means and then relocking the positioning means to the catheter.

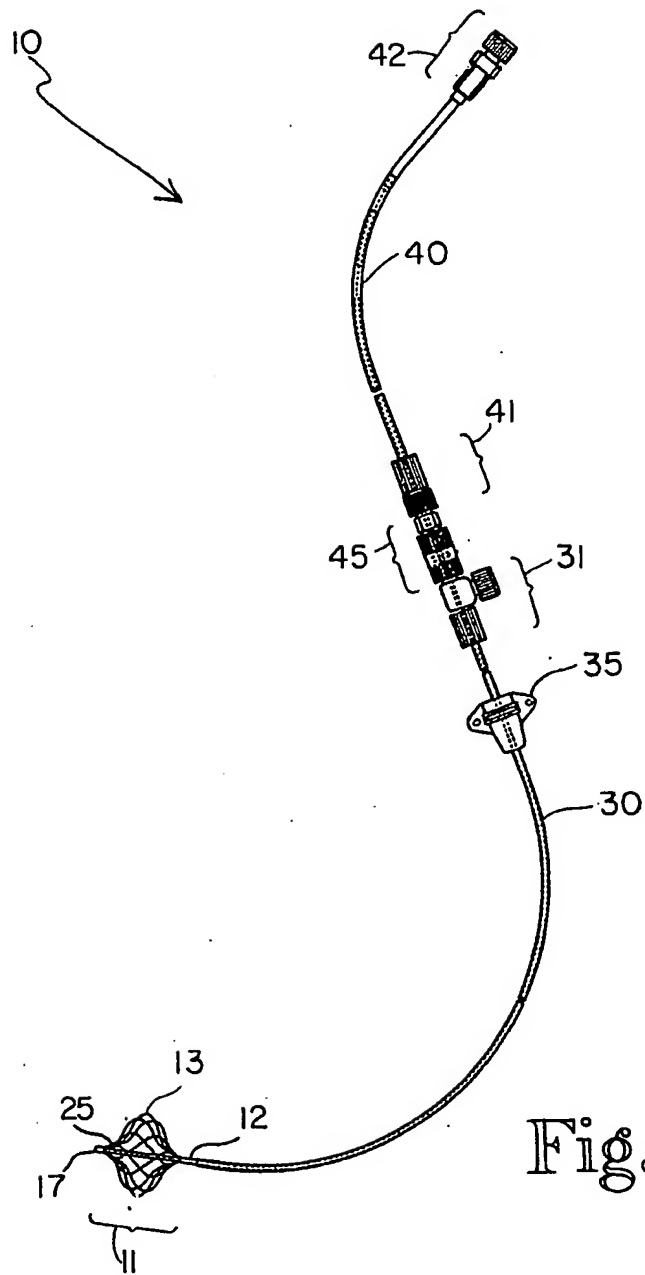


Fig. 1

This invention relates generally to apparatus for filtering blood in a blood vessel of a patient.

Blood clot filtering devices have heretofore been provided to filter blood for clots such as emboli and thrombi in a patient's blood vessel. Certain of these devices were designed to be permanently remotely placed in a blood vessel and included an anchoring means to prevent the migration of the filter from one point to another within the blood vessel. Once the filtering device was remotely placed within the vessel, the device was left indefinitely. An example of such a blood clot filtering device is disclosed in U.S. patent No. 4,619,246 issued to Molgaard-Nielsen et al. This reference shows the use of a collapsible filter basket adapted to be introduced into a blood vessel for the purpose of entrapping thrombi and emboli in the blood flowing through the vessel. The Molgaard-Nielsen device is designed to be placed remotely within a blood vessel. A plurality of anchoring legs are secured to a filter basket. The free end of each leg is bent outwardly to form a hook. When the filter basket is positioned in a blood vessel, each hook penetrates slightly into the wall of the vessel so as to hold the filter basket in position.

A device described by Driller et al. in a 1976 technical article is another example of a permanently placed vena cava filter. Such device consists of an open cone formed by straight strands of thin stainless steel wire. Each wire strand has three barbs at the tip to hold the filter basket at one location within the vessel. The strands are joined together at a central hub. In order to place the filter, a plug-ended wire guide is inserted into a length of polyethylene tubing. The collapsed filter is placed in the distal end of a length of polyethylene tubing with the filter hub in the proximal position. The plug-end of the wire guide is then brought into contact with hub of the filter. A Touhy clamp is attached to the proximal end of the tubing. The Touhy clamp permits the plug-ended guide to be securely held a few centimeters proximal the filter while the catheter is advanced. In this way the filter will not be inadvertently ejected. The loaded tubing is then introduced into the jugular vein and advanced under fluoroscopy into the subrenal inferior vena cava. The Touhy clamp is loosened and the plug-end of the wire guide is then advanced to contact the filter. The filter is ejected by withdrawing the tube sleeve while the filter is kept stationary during ejection by the plug-ended wire guide. The strands spring out as the tubing is withdrawn from about the filter. The guide wire and tubing are then withdrawn.

Another device which is designed to filter blood for clots in a blood vessel of a patient is described by Major et al. in a 1974 technical article. This device consists of a multiple ribbed catheter which is introduced through the saphenous vein. After passage into the vena cava, the ribs of the catheter are extended to contact the cava wall. This produces a sieve

through which blood will flow but which will entrap emboli. After the filtering portion is positioned in the vena cava, the tubing which extends proximally from the patient's body is severed and the device is left in place indefinitely until the patient's risk of pulmonary embolism had passed.

The above and other similar prior art devices have the disadvantage that the filter remains in contact with the interior wall of the vena cava for a substantial period of time at the same location with the result that the filter becomes endothelialized and hence attached to the interior wall of vena cava. This condition tends to block flow of blood in the vena cava.

An embodiment of the present invention involves an apparatus for filtering blood in a blood vessel of a patient which comprises a filter and a positioning means connected to the filter for positioning the filter at a location within the blood vessel. In addition, the apparatus comprises means for guiding a portion of the positioning means within the blood vessel and means for anchoring the guiding means to an object outside of the blood vessel. The apparatus further includes a means for releasably locking the positioning means to the guiding means thereby allowing the filter to be readily repositioned from a certain location to another location within the blood vessel with the positioning means.

An object of the present invention is to provide an improved apparatus for filtering blood.

Still another object of the present invention is to provide apparatus for filtering blood in which the filter does not become endothelialized and hence attached to the vena cava wall.

Other objects and benefits of the present invention can be discerned from the following written description and accompanying drawings, given by way of example only.

FIG. 1 is a side elevational view of the apparatus for filtering blood in a blood vessel of a patient of the present invention wherein the filter basket is in its expanded and relaxed state and further the sliding lock assembly is in its unlocked position.

FIG. 2 is a side elevational view of the positioning assembly of the apparatus for filtering blood of FIG. 1 wherein the filter basket is in its collapsed and unrelaxed state and the sliding lock assembly is in its unlocked position.

FIG. 3 is a side elevational view of the positioning assembly of the apparatus for filtering blood in a blood vessel of a patient of FIG. 1 wherein the filter basket is in its expanded and relaxed state and the sliding lock assembly is in its locked position.

FIG. 4 is a fragmentary, median section through a human body from the left and right thighs upward and illustrates a medical procedure performed in accordance with the preferred embodiment of the present invention. FIG. 4 shows the apparatus of FIG. 1 partially advanced into a blood vessel of a patient

where the filter is expanded and located in the vena cava. FIG. 4 further shows, in phantom, the expanded filter at another location subsequent to repositioning the filter in accordance with the method of the present invention.

FIG. 5A is an enlarged fragmentary view of the vena cava and distal end portion of the filtering apparatus of FIG. 4. FIG. 5A further shows, in phantom, the expanded filter at another location subsequent to repositioning the filter in accordance with the method shown in FIG. 4.

FIG. 5B is an enlarged view of the proximal end portion of the filtering apparatus of FIG. 4. FIG. 5B further shows, in phantom, the proximal end portion of the positioning assembly of the filtering apparatus at another location subsequent to repositioning the filter in accordance with the method shown in FIG. 4.

Referring now to FIG. 1, there is illustrated an apparatus for filtering blood in a blood vessel of a patient which is generally designated by the numeral 10. Apparatus 10 includes a collapsible filter basket 11, a positioning assembly 12, a catheter 30, an anchoring device 35, a connecting tube 40 and a Touhy-Borst fitting 45.

As shown in FIGS. 2 and 3, filter basket 11 is comprised of a plurality of thin resilient wires 13 composed of a stainless steel alloy. Wires 13 are interconnected at each end of filter basket 11 by means of a pair of ferrules 17 and 18 which are respectively secured to the wires by any appropriate means, such as brazing. Ferrule 17 extends 3.0 millimeters in length while ferrule 18 extends 5.0 millimeters in length. FIGS. 1, 3 and 4 show filter basket 11 in its expanded and relaxed state while FIG. 2 shows filter basket 11 in its collapsed and unrelaxed state. Filter 11 is 3.3 centimeters in length in its expanded state and 6.0 centimeters in its collapsed state. Connected to filter basket 11 is positioning assembly 12 as shown in FIGS. 2 and 3. Positioning assembly 12 comprises a central wire 15, a short segment of wire guide coil 16, a sliding lock assembly 23, a filter expander assembly 19, a short segment of cannula 25 and ferrule 17.

Central wire 15 extends 113.0 centimeters in length and is connected at one of its ends to ferrule 17 and at its other end to coil segment 16. Coil segment 16 is 1.0 centimeter in length and has an outer diameter of 0.052 inch. Central wire 15 extends through but is not fixedly attached to sliding lock assembly 23, expander assembly 19, filter basket 11 and cannula segment 25.

Expander assembly 19 is comprised of a ferrule 21, a segment of wire guide coil 20 and ferrule 18. Ferrule 21 is 1.0 centimeters in length. Coil segment 20 is 99 centimeters in length and has an outer diameter of 0.052 inch. Coil segment 20 is composed of a stainless steel alloy and has a passageway therethrough as alluded to above. Coil segment 20 is secured at

one end to ferrule 18 and at the other end to ferrule 21 by any appropriate means, such as brazing. Ferrules 18 and 21 also have passageways therethrough. Coil segment 20 includes a section 27 in which the coil is stretched as shown in FIGS. 2 and 3. Stretched section 27 extends 20.0 centimeters in length and is located intermediate the ends of coil segment 20. The proximal end of stretched section 27 is 29.0 centimeters in distance from the distal end of ferrule 21.

Cannula segment 25 is positioned concentrically with central wire 15 and within the interior of filter basket 11. The length of cannula segment 25 is 3.0 centimeters. Cannula segment 25 limits the axial displacement of expander assembly 19 toward ferrule 17 along central wire 15. The purpose of this limitation is to allow filter basket 11 to be easily deployed to a desired optimal shape and size without the need for visual aid.

Once filter basket 11 is deployed to its desired optimal shape and size, sliding lock assembly 23 can be used to maintain filter basket 11 in that state. Sliding lock assembly 23 is comprised of a short segment of wire guide coil 14 and a slightly larger segment of cannula 22. The length of coil segment 14 is 3.5 centimeters and the length of cannula segment 22 is 4.0 centimeters. The outer diameter of coil segment 14 is 0.052 inch. Coil segment 14 and cannula segment 22 each has a passageway therethrough and is concentrically positioned relative to central wire 15. Cannula segment 22 is positioned adjacent and affixed to the interior of coil segment 14. A small portion 24 of cannula segment 22 extends beyond the distal end of coil segment 14. The length of small cannula portion 24 is 0.25 centimeters. Cannula segment 22 has an outer diameter slightly larger than the inner diameter of ferrule 21. The outer diameter of cannula segment 22 is .020 inch and the inner diameter of ferrule 21 is .033 inch. As a result, when it is desired to maintain filter basket 11 at its optimal shape and size, sliding lock assembly 23 can be slid over central wire 15 towards ferrule 21 to ultimately wedge small cannula portion 24 of cannula 22 into the interior of the proximal end portion of ferrule 21 thus forcing the interior of small cannula portion 24 to grasp central wire 15 in a friction fit and consequently prevent expander assembly 19 from being proximally axially displaced relative to central wire 15. As a result, since the proximal end of filter basket 11 is secured to the distal end of expander assembly 19, filter basket 11 is thus made highly resistant to collapse. This feature is important because filter baskets encounter various stresses during normal use due to a variety of different loads such as thrombi and emboli. The filter basket 11 is shown locked in its expanded state by sliding lock assembly 23 in FIG. 3.

When it is desired to collapse filter basket 11 such as for insertion into or removal from the blood vessel,

sliding lock assembly 23 is pulled axially over central wire 15 toward coil segment 16 thus unlocking expander assembly 19. Expander assembly 19 is then slid axially over central wire 15 toward coil segment 16 causing the proximal ends of wires 13 to advance axially over central wire 15 toward coil segment 16. The axial movement of the proximal ends of wires 13 toward coil segment 16 correspondingly causes filter basket 11 to collapse and to become longer and thinner. Sliding lock assembly 23 is shown in FIG. 2 in an unlocked position thus allowing filter basket 11 to assume a collapsed state.

Catheter 30 is nontapered and open-ended and has a proximal fitting 31 fixed thereon as shown in FIGS. 1 and 4. Catheter 30 is 60.0 centimeters in length and has an outer diameter of 0.092 inch. Fixedly secured to the outer surface and intermediate the ends of catheter 30 is a silicone rubber winged anchoring device 35. The purpose of anchoring device 35 is to anchor apparatus 10 via sutures 36 to the skin 37 of the patient as shown in FIGS. 4 and 5B.

The proximal fitting 31 is releasably attachable to a Touhy-Borst type fitting 45. Such a fitting is a commercially available device, for example, from Cook Inc. of Bloomington, Indiana, Model No. UCC-1 and includes a rubber O-ring that may be squeezed by the operation of the device to grip a wire or other member inside of the rubber O-ring. The fitting 45 is provided to releasably lock positioning assembly 12 to catheter 30 at one of a plurality of positions on the outer surface of stretched section 27 of positioning assembly 12. Stretched section 27 possesses an irregular surface onto which fitting 45 can lock. Since positioning assembly 12 can be locked to catheter 30 at one of a plurality of positions, filter 11 can be readily repositioned from a one position to another position within the blood vessel via positioning assembly 12.

A connecting tube 40 is provided to cover the portion of positioning assembly 12 which extends beyond catheter 30 and fitting 45 in order to maintain the sterility of positioning assembly 12. Connecting tube 40 is 64.0 centimeters in length and has an outer diameter of 0.125 inch. Connecting tube 40 has a proximal fitting 42 and a distal fitting 41 thereon. The distal fitting 41 is provided to releasably attach connecting tube 40 to catheter 30 via Touhy-Borst fitting 45.

A fragmentary, median section through a human body from the left and right thighs upward is shown in FIG. 4 to aid in illustrating a medical procedure performed in accordance with the preferred embodiment of the present invention. In addition, FIGS. 5A and 5B show an enlarged view of the distal and proximal end portions respectively of the blood filtering apparatus 10 as it is used in accordance with the aforementioned medical procedure shown in FIG. 4.

A portion of a nontapered open-ended catheter 30 is introduced into and guided through the femoral vein 60 and advanced through the external iliac vein

61 and the common iliac vein 62 and then into the inferior vena cava 63. The distal end of catheter 30 is advanced to the location CD1 as represented in position indicator D. The catheter can be assisted in initial placement into the femoral vein by a sheath, wire guide and dilator combination. The filter basket 11 and attached positioning assembly 12 (described above and shown in FIGS. 2 and 3) are inserted into the proximal end of catheter 30 with the filter basket end inserted first. This can be done by collapsing filter basket 11 before insertion with the aid of a short piece of tubing that has the same inner and outer diameters as catheter 30. This short piece of tubing is then removed over the proximal end of positioning assembly 12 and discarded after filter 11 is inside catheter 30.

Filter basket 11 is then advanced through the catheter, and upon exiting the distal end thereof, it changes from a collapsed to an expanded state. Once filter basket 11 is deployed to its expanded state, sliding lock assembly 23 can be used to maintain filter basket 11 in that state, as described above. The distal end of expanded filter basket 11 is then advanced to the location DI as represented on position indicator D. When the distal end of filter basket 11 is positioned as above, the proximal end of positioning assembly 12 will correspondingly be at location P1 as represented on position indicator P. In FIGS. 4, 5A and 5B, positioning assembly 12 is shown, in phantom, extending through connecting tube 40, fitting 45 and catheter 30. Once filter basket 11 and positioning assembly 12 are positioned at this desired location, the Touhy-Borst fitting 45 is used to lock together catheter 30 and positioning assembly 12. Connecting tube 40 is then slid over the portion of positioning assembly 12 which extends beyond fitting 45 in order to maintain the sterility of the positioning assembly 12. The connecting tube 40 is then secured to fitting 45. Catheter 30 is then anchored to the skin 37 of the patient with sutures 36 via the anchoring device 35. This has the effect of anchoring the entire apparatus 10 at a fixed location.

After the filter has been in place for a period of time, it may be desirable to reposition filter basket 11 within the vena cava to prevent filter basket 11 from becoming endothelialized and hence attached to the interior wall of the vena cava. The design of the present invention allows an operator to readily reposition the filter basket within the vena cava. This is accomplished by removing connector tube 40 from the proximal end portion of positioning assembly 12, loosening fitting 45 to unlock positioning assembly 12 from catheter 30, repositioning positioning assembly 12 and the attached filter basket 11, tightening fitting 45 to relock positioning assembly 12 to catheter 30 and then recovering the proximal end portion of positioning assembly 12 with connecting tube 40.

Referring to FIGS. 4, 5A and 5B, filter basket 11F

and a distal end portion 12F of positioning assembly 12 are shown, in phantom, at a repositioned location. In this repositioned location, the distal end of filter basket 11F is at location D2 as represented on position indicator D and the proximal end of positioning assembly 12 (not shown) is correspondingly at location P2 as represented on position indicator P. As is shown in FIGS. 4 and 5A, the filter basket contacts the interior wall of the vena cava at different locations after each act of repositioning in accordance with the present invention. Since the filter basket does not become endothelialized to the interior wall of the vena cava with the above procedure, it can be left in the vena cava for several weeks without damage thereto. It should be noted that before and after the repositioning of the filter basket 11 and attached positioning assembly 12, the location of the distal end of catheter 30 as represented on position indicator D is maintained at CD1. Further, before and after the repositioning of the filter basket 11 and attached positioning assembly 12, the location of the proximal end of connecting tube 40 as represented on position indicator D is maintained at CP1.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

#### Claims

1. An apparatus for filtering blood in a blood vessel of a patient comprising:
  - a filter;
  - a positioning means connected to said filter for positioning said filter at a location within said blood vessel;
  - means for guiding a portion of said positioning means within said blood vessel;
  - means for anchoring said guiding means to an object outside of said blood vessel; and
  - means for releasably locking said positioning means to said guiding means thereby allowing said filter to be readily repositioned from a certain location to another location within said blood vessel with the positioning means.
2. The apparatus of claim 1 further comprising a means for deploying said filter to a desired shape.
3. The apparatus of claim 2 further comprising a means for securing said filter at said desired shape.

4. The apparatus of claim 1 further comprising a connection tube connected to the locking means whereby the sterility of said positioning means is maintained.
5. The apparatus of claim 1 wherein said filter is collapsible.
6. The apparatus of claim 5 wherein the positioning means is locked to said guiding means with a Touhy-Borst fitting.
7. The apparatus of claim 6 wherein the guiding means is a nontapered open-ended catheter.



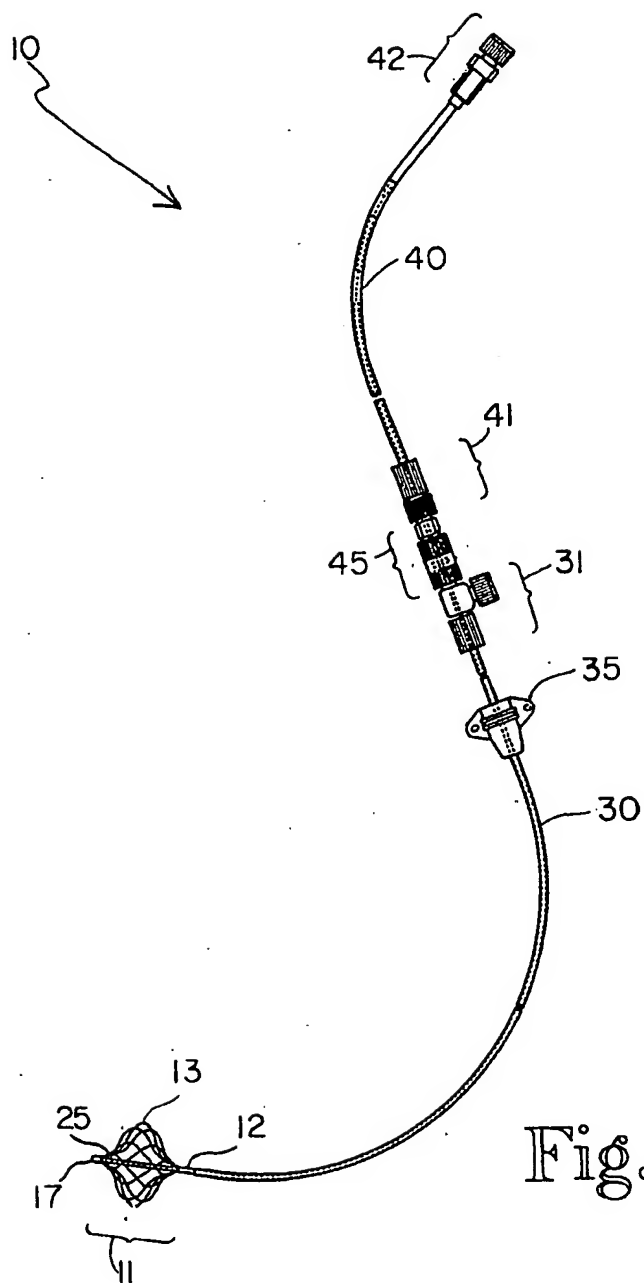


Fig. 1

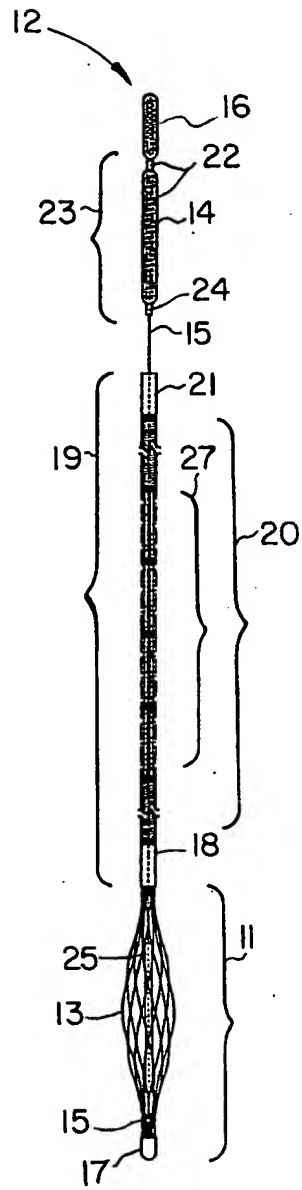


Fig. 2

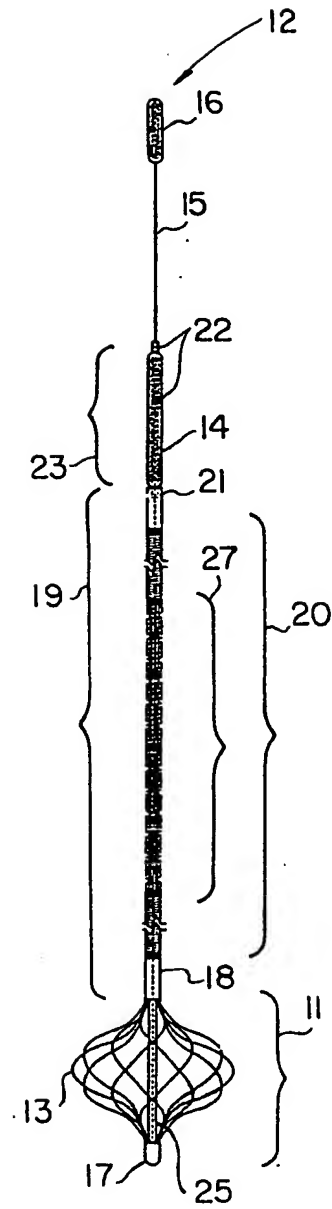


Fig. 3

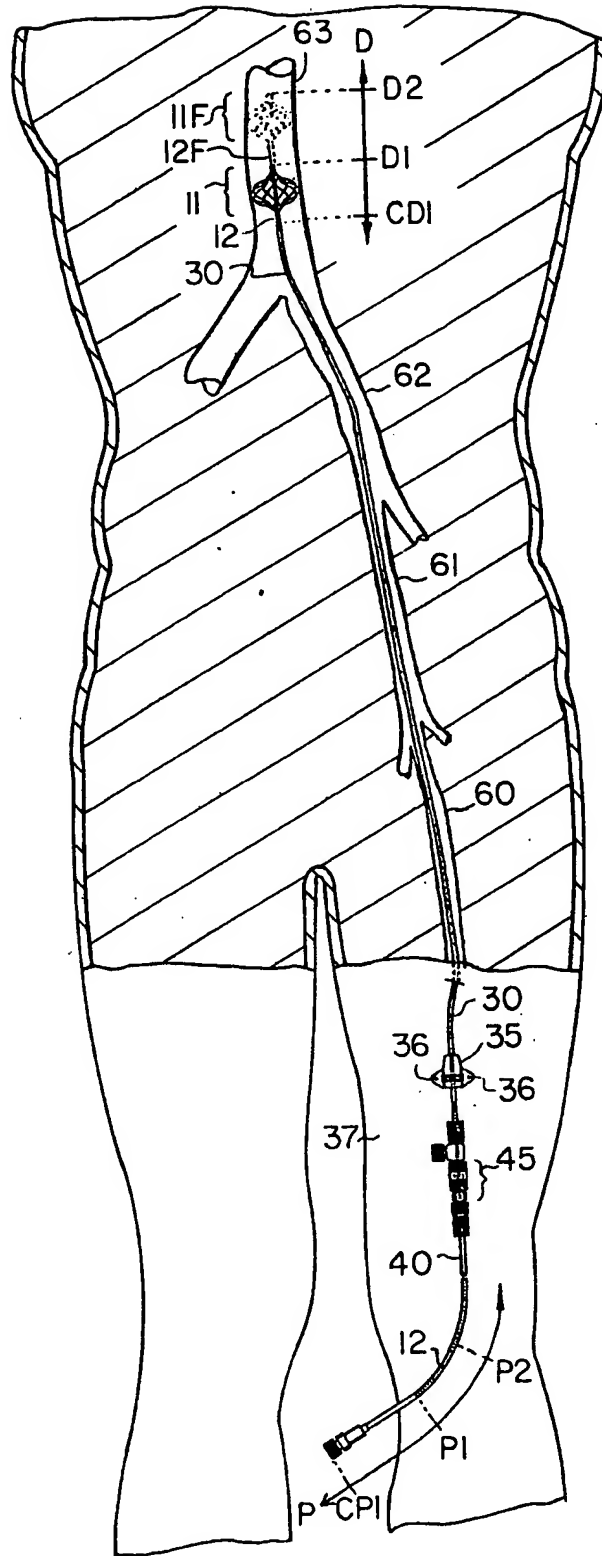


Fig.4

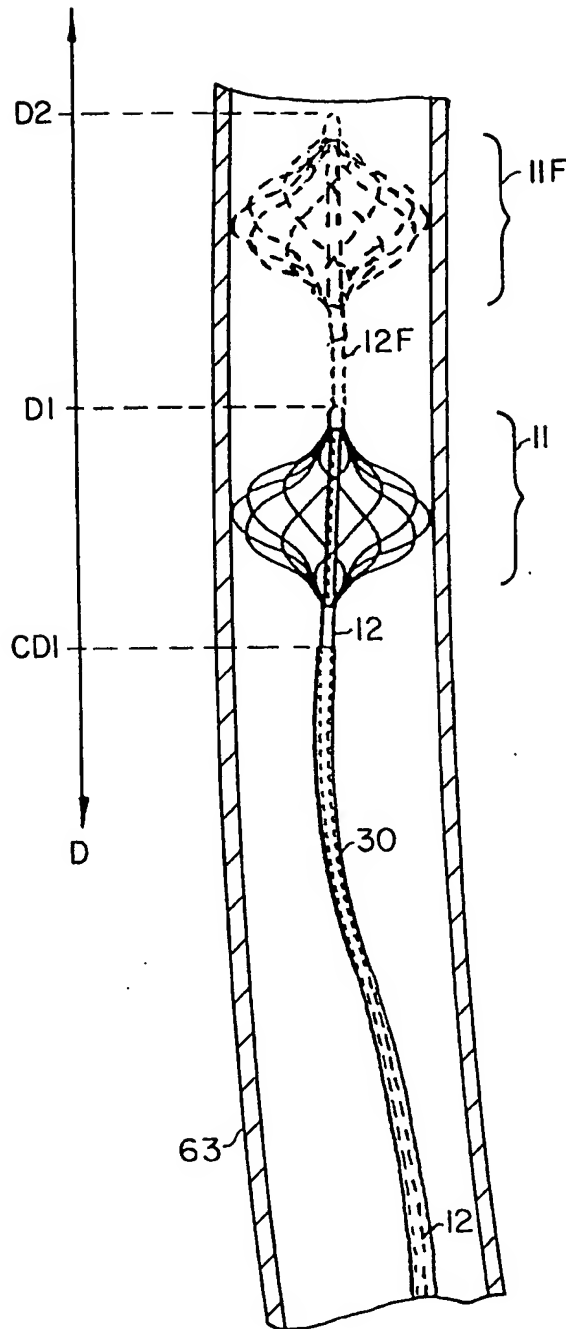
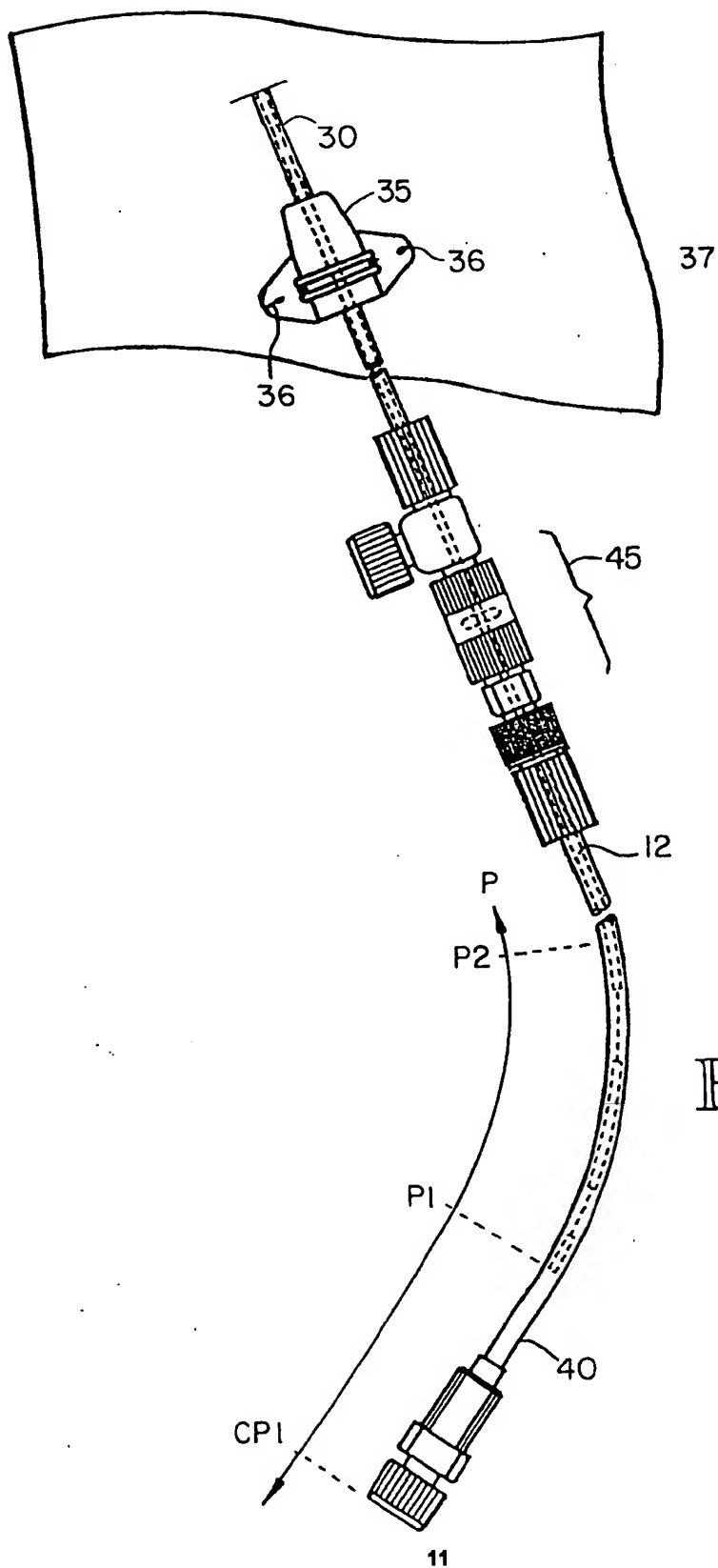


Fig. 5A



European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number

EP 91 30 7376

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CL.5)
X	FR-A-2 580 504 (PIERONNE) * abstract; claims 1-5; figures *	1-7	A61F2/02
Y	EP-A-0 321 912 (DELSANTI) * abstract; figures 2,4,6 *	1-3,5	
Y	EP-A-0 117 940 (COOK INC.) * abstract; figures *	1-3,5	
P,X	FR-A-2 657 261 (BOVYN ET AL.) * the whole document *	1-7	
P,X	FR-A-2 652 267 (PROTHIA S.A. R.L.) * the whole document *	1-7	
A	EP-A-0 093 512 (AMERICAN HOSPITAL SUPPLY CO.) * page 3, line 23 - line 29; figure 1 *	1	
			TECHNICAL FIELDS SEARCHED (Int. CL.5)
			A61F A61B A61M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 22 OCTOBER 1991	Examiner SANCHEZ Y SANCHEZ J.
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons</p> <p>A : number of the same patent family, corresponding document</p>			

EPO FORM LSO 0481 (7/90)